

**Remarks**

This is in response to the Office Action mailed 8/21/2007. Claims 1-2, 4, 6, 8-10, 29-30, 32-33, and 35-46 are pending. Claims 1, 29, 30, and 46 are independent.

***Election/Restriction***

Applicant confirms election of Group II, claims 1-20 and 26-43. Claims 21-25 have been cancelled in view of the restriction requirement.

***Double Patenting***

Claims 1, 4, 6-7, 11-12, 15-16, 18-20, 26-27, 30-31, 34-36 and 41-42 have been rejected for obviousness double patenting over claims 1, 4, 6 and 21-24 of Wang et al, US 7,128,956 (Wang '956). The rejection is traversed.

Claims 7, 11-12, 15-16, 18-20, 26-27 and 31 have been cancelled.

The cited claims of Wang '956 are directed to a catheter shaft with a pre-formed bend and a nucleating agent dispersed at least at the pre-formed bend.

Amended independent claim 1 now recites a dilatation balloon as previously recited in claim 7. Amended independent claim 30 now recites a catheter balloon, rather than a medical device part. The cited claims of Wang '956 do not make obvious a dilation balloon, or a catheter balloon, having a varying polymer composition in different parts of the balloon.

Independent claim 29 is directed to a medical device part which has a crystallization inhibitor in one portion and a crystallization enhancer in another portion, relative to the same base polymer. The cited claims of Wang '956 do not make obvious the use of a crystallization inhibitor in one portion and a crystallization enhancer in another portion of the device.

At least for these reasons withdrawal of the double patenting rejection of claims 1, 4, 6, 30, 34-36 and 41-41 over Wang '956 is respectfully requested.

***Claim Rejections - 35 USC §102***

Claims 30-31 and 41 have been rejected as anticipated by Muni et al, US 5,316,706. The rejection is traversed.

Claim 31 has been cancelled.

Muni pertains to extruded catheter tubing having portions along its length differentially crystallized by post-extrusion thermal treatment. It does not relate to catheter balloons or to compositions for forming balloons or balloon parisons.

Claim 30 has been amended to recite a catheter balloon formed of a polymer material composition that includes at least one crystallization modifier which varies in concentration over a portion of the balloon. Muni et al does not disclose or suggest a catheter balloon having such a varied composition. At least for these reasons Muni et al does not anticipate currently pending claims 30 and 41.

Claims 1-4, 6-7, 11-20, 26-27, 30-37 and 41-42 have been rejected as anticipated by Wang, US 7,128,956. The rejection is traversed.

Claims 3, 7, 11-20, 26-27, 31, and 34 have been cancelled.

Wang '956 describes a catheter shaft with outer shaft portion having a pre-formed bend and a nucleating agent dispersed at least at the pre-formed bend.

Regarding claims 1-2, 4, 6, 30, 32-33, 35-37 and 41-42, Wang '956 does not disclose a balloon with a polymer composition that varies as recited. A balloon catheter outer shaft portion is not a balloon. At least for these reasons Wang '956 does not anticipate currently pending claims 1-2, 4, 6, 26, 30, 32-33, 35-37 and 41-42,

### ***Claim Rejections - 35 USC §102***

Claims 30, 41 and 43 have been rejected as obvious over Wang et al US '956 in view of Wang et al US 6,284,333 (Wang '333). The rejection is traversed.

Claims 30, 41 and 43, as amended specifically recite a catheter balloon.

The assertion in the Office Action is that it would be obvious to combine Wang '956 and Wang '333 to impart higher strength and resistance to shrinkage to the base polymer materials by adding a liquid crystal polymer (Office Action ¶16). Without acquiescing in the rationale of the rejection, the rejection is traversed at least because the involved claims no longer pertain to catheter shaft portions as described in Wang '956. Compositions employed to make catheter balloons have unique requirements, different from those of catheter shaft bend-portions. Nothing in Wang '956

Nothing in Wang '956 suggests varying an amount of a crystallization modifier along the length of a balloon and a skilled person would not be motivated to modify a balloon composition based on the disclosed properties of the catheter bend portions of the Wang '956 catheter shafts. Balloons have specific property requirements distinct from catheter shafts and so formulations designed for catheter shafts do not render obvious their use in balloons. At least for these reasons withdrawal of this rejection is requested.

Claims 1-4, 6-7, 11-20, 26-27, 30-37, and 41-42 have been rejected as obvious from Muni et al in view of nucleating agents disclosed by applicant and Satchell et al, US 4,276,250. The rejection is traversed.

Claims 3, 7, 11-20, 26-27, 31, and 34 have been cancelled.

The assertion in the Office Action is that the combined teachings of these citations would have led a skilled person to modify crystallization of a catheter longitudinally as disclosed by Muni et al by adding a nucleating agent to the polymer composition in a selected portion along the length (Office Action ¶22). Without acquiescing in the rationale of the rejection, the rejection is traversed at least because the involved claims no longer pertain to catheter tubing portions. Nothing in Muni et al, nucleating agents disclosed by applicant, or Satchell et al suggests varying an amount of a nucleating agent along the length of a balloon. Balloons have specific property requirements distinct from catheter shafts and so formulations designed for catheter shafts do not render obvious their use in balloons. At least for these reasons withdrawal of this rejection is requested as to claims 1-2, 4, 6, 30 and 41-42.

Claims 1, 7-10, 26, 28-29, 30, 34 and 38-40 have been rejected as obvious from Muni et al in view of Sahatjian, US 5,316,706, and Satchell et al. The rejection is traversed.

Claims 7, 26, 28, and 34 have been cancelled.

The assertion in the Office Action is that the combined teachings of these citations would have led a skilled person to modify crystallization of a catheter longitudinally as disclosed by Muni et al by adding a crystallization inhibitor to the polymer composition in a selected portion along the length (Office Action ¶34). Without acquiescing in the rationale of the rejection, the rejection is traversed at least because, except for claim 29, the involved claims no longer pertain to catheter

to catheter tubing portions. Nothing in Muni et al or Satchell suggests varying an amount of a crystallization inhibitor along the length of a balloon. Balloons have specific property requirements distinct from catheter shafts and so formulations designed for catheter shafts do not render obvious their use in balloons. As to claim 29, nothing in any of the documents suggests using a crystallization enhancer in one portion of a device part and a crystallization inhibitor in another portion of that part. At least for these reasons withdrawal of this rejection is requested as to claims 1, 8-10, 29-30 and 38-40.

*New claims*

Claims 44 and 45 depend from claim 30 and respectively recite that the one crystallization modifier varies in concentration in the polymer material composition "through the thickness of the balloon" or "along the length of the balloon." See original claim 31; Figs, 1 and 2, respectively, and 17:22-18:32.

Claims 44 and 45 are seen to be patentable over the cited documents at least for the reasons given for claim 30.

Respectfully submitted,

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